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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,535	05/31/2000	Jean-Christophe Francis Audonnet	454313-2335.1	6015

20999 7590 01/03/2002

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/586,535	Applicant(s) AUDONNET ET AL.	
	Examiner Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-39* is/are pending in the application.

4a) Of the above claim(s) *14,27 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15-17,20-26,28-35 and 39* is/are rejected.

7)☒ Claim(s) *18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on October 17, 2001 has been entered as Paper #10. The Examiner assigned to your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Claims 1-11 have been canceled, claims 12-39 are newly added. Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the chemical structure of the polymer in claim 14 is distinct from the original recited adjuvant. Newly submitted claims 27 and 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the numerous pathogens recited in claim 14 is distinct from the original recited PCV.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 and dependent claim 36, claims 27 and 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 12, 13, 15-26, 28-35, 37, and 39 are under current examination.

Priority

Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of foreign priority claimed in the provisional Application No.

60,138,352 under 35 U.S.C. 119(a)-(d), a claim for such foreign priority must be made in this application, and applicants are responsible for providing certified translation for such priority papers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

ENABLEMENT REJECTION

The prior rejection of claims 1-11 is withdrawn in view of the cancellation of the claims. The newly added claims have limited the immunogenic preparation to particular fragments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claims 1 and 7-9 under 35 U.S.C. 102(b) as being anticipated by *Okada et al* is withdrawn because *Okada et al* do not teach an immunogenic preparation of PCV.

The prior rejection of claims 1 and 7-9 under 35 U.S.C. 102(b) as being anticipated by *Meehan et al* is withdrawn because *Meehan et al* do not teach an immunogenic preparation of PCV.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Claims 12, 20-26, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Allan et al* (US 6,217,883), in view of *Eppstein et al* (US 4,946,787).

These claims are drawn to an immunogenic preparation comprising a complex of at least one plasmid encoding and capable of expressing in a porcine host an isolated nucleic acid molecule selected from the group consisting of ORF1 and ORF 2 of PCVII, or an immunogen from a porcine pathogenic agent other than PCV-2 or PCV-1, and an adjuvant comprising a cationic lipid formula. Claim 39 is drawn to a method comprising administering to a porcine host the immunogenic preparation.

Allan et al teach a porcine circovirus vaccine comprises immunogenic epitopes a plurality of porcine circoviruses (claim 27), particularly type I or II PCV (column 5, lines

7-13), and preferably PCVII of ORFs 1-13 (claims 2 and 12) and an adjuvant acceptable from the veterinary point of view (column 6, line 39). *Allan et al* further teach a method for inducing an immunological response comprising administering to a porcine said vaccine. *Allan et al* do not teach the particular adjuvant formula recited in claim 12.

Eppstein et al teach a "formula I", which is embraced by the formula of claim 2. They teach to improve recombinant viral vector delivery by using formula I (column 3), "THE MOST DESIRABLE TRANSFECTION METHOD WOULD INVOLVE ONE THAT GIVES VERY HIGH EFFICIENCY WITHOUT THE INTRODUCTION OF ANY TOXIC OR INFECTIOUS SUBSTANCES AND BE SIMPLE TO PERFORM WITHOUT A SOPHISTICATED APPARATUS. THE METHOD THAT WE DESCRIBE SATISFIES ALL OF THESE CRITERIA".

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Allan et al*, by simply including one of the adjuvant acceptable from the veterinary point of view, such as formula I as taught by *Eppstein et al* with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 13, 20-26, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Allan et al* (US 6,217,883), in view of *Neurath et al* (US 6,165,493).

These claims are drawn to an immunogenic preparation comprising a complex of at least one plasmid encoding and capable of expressing in a porcine host an isolated nucleic acid molecule selected from the group consisting of ORF1 and ORF 2 of PCVII, or an immunogen from a porcine pathogenic agent other than PCV-2 or PCV-1, and an

adjuvant comprising a carbomer. Claim 39 is drawn to a method comprising administering to a porcine host the immunogenic preparation.

Allan et al teach a porcine circovirus vaccine comprises immunogenic epitopes a plurality of porcine circoviruses (claim 27), particularly type I or II PCV (column 5, lines 7-13), and preferably PCVII of ORFs 1-13 (claims 2 and 12) and an adjuvant acceptable from the veterinary point of view (column 6, line 39). *Allan et al* further teach a method for inducing an immunological response comprising administering to a porcine said vaccine. *Allan et al* do not teach the particular adjuvant carbomer.

Neurath et al teach methods and compositions for viral vaccine using recombinant viral particles and an adjuvant. They teach a vaccine preparation mixture comprising a carbomer (column 28).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Allan et al*, by simply including one of the adjuvant acceptable from the veterinary point of view, such as carbomer as taught by *Neurath et al,* with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 12, 15-17, 20-26, 28-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Allan et al* (US 6,217,883), in view of *Dubensky, Jr. et al* (US 6,015,694).

These claims are drawn to an immunogenic preparation comprising a complex of at least one plasmid encoding and capable of expressing in a porcine host an isolated nucleic acid molecule selected from the group consisting of ORF1 and ORF 2 of PCVII, or an immunogen from a porcine pathogenic agent other than PCV-2 or PCV-1, and an adjuvant comprising a cationic lipid of DMRIE; wherein DMRIE is coupled to DOPE or a neutral lipid, wherein the optimal ratio of DMRIE:DOPE ranges from 95:5 to 5:95. Claim 39 is drawn to a method comprising administering to a porcine host the immunogenic preparation.

Allan et al teach a porcine circovirus vaccine comprises immunogenic epitopes a plurality of porcine circoviruses (claim 27), particularly type I or II PCV (column 5, lines 7-13), and preferably PCVII of ORFs 1-13 (claims 2 and 12) and an adjuvant acceptable from the veterinary point of view (column 6, line 39). *Allan et al* further teach a method for inducing an immunological response comprising administering to a porcine said vaccine. *Allan et al* do not teach the particular adjuvant recited in the claims.

Dubensky, Jr. et al teach a method for stimulating an immune response using recombinant viral particles and adjuvant. They teach prepare a gene delivery vehicles complexed with cationic liposomes, which may be prepared from a mixture of positively charged (DMRIE) and negatively charged lipids, neutral lipids (DOPE) and cholesterol or similar sterol, the preferred ratio of DMRIE to DOPE is 9:1 to 1:9, which is encompassed by the instant claims (columns 156 and 157). Although *Dubensky, Jr. et al* do not teach the particular plasmid:DMRIE weight ratios recited in the instant claims,

the experimentation to obtain these ratios are considered as routine to optimize the delivery condition.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Allan et al*, by simply including one of the adjuvant acceptable from the veterinary point of view, such as DMRIE/DOPE as taught by *Dubensky Jr. et al,* with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim Objections

Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Crouch can be reached on 703-308-1126. The fax numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
December 19, 2001

JAMES KETTER
PRIMARY EXAMINER